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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,326	06/17/2002	Pankaj Madganal Vadgama	0380-P02810USO	3591
110	7590	11/15/2004	EXAMINER	
DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			NOGUEROLA, ALEXANDER STEPHAN	
			ART UNIT	PAPER NUMBER
			1753	

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/049,326

Applicant(s)

VADGAMA, PANKAJ MADGANAL

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) 1-10 and 12-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 June 2002 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 7, 8, and 12-18 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Gross et al. (WO 98/58250 A2) ("Gross I"). See page 19, first and second full paragraphs.

For claim 12 also see page 19, lines 18-20.

For claims 13 and 14 note that Gross I discloses a Nafion membrane (page 19, lines 21-28), which reduces acetaminophen interference as evidenced by the abstract of Moatti-Sirat et al. ("Reduction of acetaminophen interference in glucose sensors by a composite Nafion membrane: demonstration in rats and man," *Diabetologia*, volume 37, number 6, June 1994, pp. 610-616).

For claim 15 note that Gross I also discloses polyurethane membrane. See page 19, lines 21-28.

For claim 16 note that how the cavities are made is a product-by-process limitation that does not patentably distinguish the claimed invention from the invention of the prior art unless

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there is a material difference in the resulting product, especially since claim 16 allows for three substantially different methods to be used for producing the cavities. MPEP 2113.

For claim 17 see page 19, lines 18-20.

For claim 18 note that how the cavities are made is a product-by-process limitation that does not patentably distinguish the claimed invention from the invention of the prior art unless there is a material difference in the resulting product. MPEP 2113.

3. Claims 1-5, 7, 8, 9, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al. (WO 96/14026 A1). See page 39, lines 17-27.

For claim 9 note that the enzyme matrix is formed from a casting solution of Nafion and enzyme. See page 9, lines 21-24.

For claim 16 note that how the cavities are made is a product-by-process limitation that does not patentably distinguish the claimed invention from the invention of the prior art unless there is a material difference in the resulting product, especially since claim 16 allows for three substantially different methods to be used for producing the cavities. MPEP 2113. In any event Gross II discloses laser drilling to produce the cavities. See page 39, ll. 21-27.

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al. (WO 98/58250 A2) ("Gross I"). Gross I discloses a sensor device as required by claim 1. See page 19, first full paragraph. Gross I does not mention an outer diameter range for the wire, although Gross I does disclose an example needle diameter of 300  $\mu\text{m}$ , which is in microns as is the claimed diameter range, and Gross I states "it will be appreciated that a wide variety of dimensions can be employed as required." See page 20, lines 5-9. Mere change in size is not in itself patentable. MPEP 2144.04.IV.A. Barring evidence to the contrary, such as unexpected results, it would have been obvious to one with ordinary skill in the art at the time the invention was made to scale the dimension of the needle so as to minimize pain or discomfort to the patient, but also have a large enough surface area for adequate exposure to body tissue or fluid.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al. (WO 96/14026 A1) (Gross II). Gross II discloses a sensor device as required by claim 1. See page 39, lines 17-27. Gross II does not mention an outer diameter range for the wire, although Gross II does disclose an example needle diameter of 300  $\mu\text{m}$ , which is in microns as is the claimed diameter range, and Gross II states "it will be appreciated that a wide variety of dimensions can be employed as required." See page 20, lines 5-9. Mere change in size is not in itself patentable. MPEP 2144.04.IV.A. Barring evidence to the contrary, such as unexpected results, it would have been obvious to one with ordinary skill in the art at the time the invention was made to scale the dimension of the needle so as to minimize pain or discomfort to the patient, but also have a large enough surface area for adequate exposure to body tissue or fluid.

8. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al. (WO 98/58250 A2) ("Gross I") in view of Jung et al. ("Polymeric Mercaptosilane-Modified Platinum Electrodes for Elimination of Interferants in Glucose Biosensors," *Anal. Chem.* 1996, 68, 591-596) ("Jung"). Gross I discloses a sensor device as required by claim 1. See page 19, first full paragraph. Gross I does not mention retaining the enzyme in the cavities by cross-linking. Jung teaches retaining enzyme on a wire electrode by cross-linking. See the abstract. It would have been obvious to one with ordinary skill in the art at the time the invention was made to immobilize the enzyme on the wire electrode as taught by Jung, which involves cross-linking the enzyme on the electrodes, in the invention of Gross I because as taught by Jung the electrode will have a linear response range over a large concentration range, be stable for more than 5 days, and have excellent selectivity for the analyte against interferants. See the abstract.

For claim 10 note that Jung uses gluteraldehyde in the cross-linking of the enzyme. See the abstract.

9. Claims 10, 12-15, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al. (WO 96/14026 A1) (Gross II) in view of Jung et al. ("Polymeric Mercaptosilane-Modified Platinum Electrodes for Elimination of Interferants in Glucose Biosensors," *Anal. Chem.* 1996, 68, 591-596) ("Jung").

Addressing claims 10 and 12-15, Gross II discloses a sensor device as required by claim 1. See page 39, lines 17-27. Gross II does disclose retaining the enzyme in the cavities by cross-linking; however Jung uses Nafion, not gluteraldehyde. See page 39, lines 21-24. Jung teaches retaining enzyme on a wire electrode by cross-linking. See the abstract. It would have been obvious to one with ordinary skill in the art at the time the invention was made to immobilize the enzyme on the wire electrode as taught by Jung, which involves cross-linking the enzyme on the electrodes with gluteraldehyde, in the invention of Gross II because as taught by Jung the electrode will have a linear response range over a large concentration range, be stable for more than 5 days, and have excellent selectivity for the analyte against interferants. See the abstract.

For claim 12 note that the enzyme immobilization of Jung involves a membrane over the enzyme that improves linearity of sensor response. See the abstract and Figure 1.

For claims 13-15 note that the outer member is polyurethane.

Addressing claim 17, Gross II discloses a sensor device as required by claim 1. See page 39, lines 17-27. Gross II does not mention covering the wire electrode with a coating of insulating material. Jung teaches coating a wire electrode with Teflon except over the portion of the electrode that retains enzyme. See Figure 1. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a coating as taught by Jung in the invention of Gross II because this will prevent undesirable secondary reactions with the electrode and decomposition of the electrode, which Gross II recognized as possible. See page 38, last paragraph and page 39, first full paragraph.

Addressing claim 18, how the cavities are made is a product-by-process limitation that does not patentably distinguish the claimed invention from the invention of the prior art unless there is a material difference in the resulting product. MPEP 2113.

***International Search Report for PCT/GB00/03054***

10. US 5,660,163 was cited as an "X" reference against claim 1 and various claims that depend therefrom. The examiner considers the invention of claim 1 to be patentably distinct from the invention of US 5,660,163 because US 5,660,163 does not disclose a "wire electrode having a plurality of cavities formed along the length of the electrodes which retains the enzyme." In contrast, the sensor in US 5,660,163 comprises an electrically insulating housing



(100), such as a silicon sheath, having one cavity (102), which retains an enzyme (104). See Figure 4B and col. 8, ln. 62 – col. 9, ln. 16.

11. EP 0264210 A2 was cited as an “X” reference against claim 1 and various claims that depend therefrom. The examiner considers the invention of claim 1 to be patentably distinct from the invention of EP 0264210 A2 because EP 0264210 A2 does not disclose a “wire electrode having a plurality of cavities formed along the length of the electrodes which retains the enzyme.” In contrast, the sensor in EP 0264210 A2 comprises a probe body (16) made of a stainless steel shaft with a single cavity (17) in its upper surface (18), which exposes several electrodes to the sample. See col. 5, ll. 1-15 and col. 5, ll. 41-48. The pores (34) shown in Figure 4 are not on a wire electrode but are on a thick film electrode. See col. 5, ll. 40-45 and col. 6, ll. 13-20.

### ***Priority***

12. If applicant desires priority under 35 U.S.C. 371 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression “now Patent No. \_\_\_\_\_” should follow the filing date of the

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parent application. If a parent application has become abandoned, the expression “now abandoned” should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was


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unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Alex Noguerola  
Primary Examiner  
AU 1753  
November 10, 2004